

The amendments and new claims are fully supported by the instant specification, *e.g.*, see page 9, lines 9-26, page 10, line 10 to page 11, line 2, page 11, line 4 to page 12, line 12, page 15, line 19 to page 19, line 34, page 26, line 14 to page 28, line 10, page 39, line 19 to page 41, line 8, and do not represent new subject matter.

The Examiner has required an election under 35 U.S.C. § 121 of one of the following groups:

- I. Claims 1-13, 46, and 47, drawn to a method for treating cancer comprising administering an antibody conjugate, classified in class 530, subclass 391.7;
- II. Claims 14, 16-19, and 41-45, drawn to antibodies and pharmaceutical compositions comprising antibodies, classified 435, subclass 130.1 and 178.1;
- III. Claims 20-34, drawn to a method for detecting cancer comprising administering a labeled antibody, classified in class 530, subclass 391.3;
- IV. Claims 35-40, drawn to a method of depleting cancer cells *in vitro* comprising contacting an antibody to a sample, classified in class 530, subclass 388.3; and
- V. Claims 15-17 and 19, drawn to pharmaceutical compositions comprising nucleic acids encoding an antibody, classified in class 536, subclass 25.53.

The Examiner contends that the inventions of Groups I-V are distinct from each other.

Applicants respectfully traverse the Restriction Requirement, in part, and assert that Claims 20-34 in Group III, drawn to methods for detecting cancer comprising administering labeled antibody, and amended Claims 43-45 in Group II, drawn to kits for use in the methods for detecting cancer comprising administering labeled antibody, should be examined in a single application. Applicants respectfully assert that a single search would identify any relevant art pertaining to methods for detecting cancer comprising administering labeled antibody and kits containing labeled antibodies for use in accordance with such methods. Accordingly, Applicants respectfully request that the Restriction Requirement Under 35 U.S.C. § 121 be modified to permit all present claims, *i.e.*, Claims 20-34, 41-45, and 48-57, to be examined in one application.

In order to be fully responsive, however, Applicants hereby elect, with traverse, to prosecute the claims of Group III, Claims 20-34, drawn to methods for detecting cancer comprising administering labeled antibody, without prejudice to Applicants' right to pursue


the non-elected subject matter in other applications. Presently pending claims 20-34 and 48-56 are within this elected Group.

Entry of the amendments and remarks made herein is respectfully requested. The Examiner is invited to contact the undersigned with any questions concerning the foregoing.

Examiner's attention is directed to an Information Disclosure and modified PTO-1449 Form listing references AA-BL together with a copy of each of references AA-BI which were submitted on January 26, 2000. It is requested that all of the references be made of record in the file.

Respectfully submitted,

Date November 16, 2000


Geraldine F. Baldwin 31,232
(Reg. No.)

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Enclosure

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Taylor et al.



Application No.: 09/392,380

Group Art Unit: 1642

Filed: September 9, 1999

Examiner: O'Hara

For: ANTIBODIES TO A TUMOR-
ASSOCIATED SURFACE
ANTIGEN FOR DELIVERY OF
DIAGNOSTIC AND
THERAPEUTIC AGENTS

Attorney Docket No.: 9426-019

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FEE TRANSMITTAL SHEET

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

The fee required to be filed with the accompanying amendment of even date herewith concerning the above-identified application has been estimated to be \$126.00.

The claim amendment fee has been estimated as shown below:

(Col. 1)		(Col. 2)		(Col. 3)		SMALL ENTITY		OTHER THAN A SMALL ENTITY	
CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NO PREVIOUSLY PAID FOR		PRESENT EXTRA		RATE	ADDIT. FEE	OR	RATE
TOTAL	54	MINUS	47	=	7	× 9	\$	× 18	\$
INDEP.	4	MINUS	9	=	-5	× 40	\$	× 80	\$
<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEP. CLAIM						+130	\$	+ 260	\$
						TOTAL	\$	OR TOTAL	\$
									126.00

Please charge the required fee to Pennie & Edmonds LLP Deposit Account No. 16-1150.
A copy of this sheet is enclosed.

Respectfully submitted,

Date: November 16, 2000

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Enclosure



EXHIBIT A

PENDING CLAIMS AS OF NOVEMBER 16, 2000
U.S. PATENT APPLICATION SERIAL NO. 09/392,500
ATTORNEY DOCKET NO. 9426-019

20. A method for detecting cancer comprising:
- a) administering to a subject an effective amount of a labeled antibody which specifically binds to C3b(i) or a labeled antibody to C3b(i) covalently linked to a second molecule;
 - b) waiting for a time interval following the administration to permit the labeled antibody to preferentially concentrate at any cancerous site in the subject;
 - c) determining background level; and
 - d) detecting the labeled antibody in the subject, wherein detection of the labeled antibody above the background level indicates the presence of a cancer.
21. The method of Claim 20, 48 or 49 in which the subject is a human.
22. The method of Claim 20, 48 or 49 in which the labeled antibody is a monoclonal antibody.
23. The method of Claim 20, 48 or 49 in which the labeled antibody is a humanized antibody.
24. The method of Claim 20, 48 or 49 in which the labeled antibody is labeled with a radioisotope.
25. The method of Claim 20 in which the labeled antibody is detected *in vivo*.
26. The method of Claim 20 or 48 in which time interval is 6 hours to 48 hours.
27. The method of Claim 20, 48 or 49 in which the labeled antibody is administered intravenously.

28. The method of Claim 20 which further comprises repeating steps (a) through (d) at monthly or yearly intervals.

29. A method for detecting cancer in a subject, comprising imaging said subject at a time interval after administering to said subject an effective amount of a labeled antibody which specifically binds to C3b(i) or a labeled antibody covalently linked to a second molecule which antibody specifically binds to C3b(i), said time interval being sufficient to permit the labeled antibody to preferentially concentrate at any cancerous site in said subject, wherein detection of the labeled antibody localized at said site in the subject indicates the presence of cancer.

30. The method of Claim 29 or 50 in which the subject is a human.

31. The method of Claim 29 or 50 in which the labeled antibody is a monoclonal antibody.

32. The method of Claim 29 or 50 in which the labeled antibody is a humanized antibody.

33. The method of Claim 29 or 50 in which the labeled antibody is labeled with a radioisotope.

34. The method of Claim 29 or 50 in which time interval is 6 hours to 48 hours.

43. A kit comprising, in one or more containers, an antibody to C3b(i) or an antibody to C3b(i) covalently conjugated to a second molecule with instructions for use in the method of claim 20 or 29.

44. The kit of Claim 48, 49 or 50 further comprising IgM or IgG antibody.

45. The kit of Claim 44, 48, 49 or 50 further comprising one or more complement components.

48. A method for detecting cancer comprising:

- a) administering to a subject plasma, one or more complement components, IgG antibody or IgM antibody;
- b) administering to said subject an effective amount of a labeled antibody which specifically binds to C3b(i);
- c) waiting for a time interval following step (b) to permit the labeled antibody to preferentially concentrate at any cancerous site in the subject;
- d) determining background level; and
- e) detecting the labeled antibody in the subject, wherein detection of the labeled antibody above the background level indicates the presence of a cancer.

49. A method for detecting cancer comprising:

- a) administering to a subject plasma, one or more complement components, IgG antibody or IgM antibody;
- b) waiting for a time interval following step (a);
- c) administering to said subject an effective amount of a labeled antibody which specifically binds to C3b(i);
- d) waiting for a time interval following step (c) to permit the labeled antibody to preferentially concentrate at any cancerous site in the subject;
- e) determining background level; and
- f) detecting the labeled antibody in the subject, wherein detection of the labeled antibody above the background level indicates the presence of a cancer.

50. A method for detecting cancer in a subject, comprising imaging said subject at a time interval after administering sequentially to said subject plasma, one or more complement components, IgG antibody or IgM antibody and an effective amount of a labeled antibody which specifically binds to C3b(i), said time interval being sufficient to permit the labeled antibody to preferentially concentrate at any cancerous site in said subject, wherein detection of the labeled antibody localized at said site in the subject indicates the presence of cancer.

51. The method of Claim 20, 48 or 49 in which the labeled antibody is a human antibody.

52. The method of Claim 29 or 50 in which the labeled antibody is a human antibody.

53. The method of Claim 48 or 49 in which the plasma, IgG antibody or IgM antibody is administered intravenously.

54. The method of Claim 48, 49 or 50 wherein at least one of the complement components is C3.

55. The method of Claim 48 which further comprises repeating steps (a) through (e) at monthly intervals.

56. The method of Claim 49 which further comprises repeating steps (a) through (f) at monthly or yearly intervals.

57. A kit comprising, in one or more containers, an antibody to C3b(i) with instructions for use in the method of claim 48, 49 or 50.